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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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John Bernard March

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EXAMINER

SNYDER, STUART

ART UNIT

PAPER NUMBER

1648

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DELIVERY MODE

06/02/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/529,917	Applicant(s) MARCH ET AL.	
	Examiner STUART W. SNYDER	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,9-16 and 19-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,9-16 and 19-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/28/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

1. Claims 1, 3-6, 9-16, and 17-21 as amended on 2/02/2010 are pending.
Cancellation of claim 17 and amendment of claims 1, 3-6, 9-16, and 17-21 is acknowledged.

Drawings

2. The drawings were received on 2/2/2010. These drawings are acceptable and objection to Figure 5 is **withdrawn**.
3. Amendment of the specification filed 2/2/2010 regarding Figure 2 is acknowledged and is sufficient to overcome the previous objection to Figure 2; objection to Figure 2 is **withdrawn**.

Claim Objections

4. Objection to claim 21 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is **withdrawn** in view of amendment of the claim.

Claim Rejections - 35 USC § 112, ¶ 1

5. Rejection of claims 1, 3-6, 9-16, and 17-21 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is **withdrawn** in view of amendment of the claims replacing the word "vaccine" to "immunogenic".

Claim Rejections - 35 USC § 112, ¶ 2

6. Rejection of claim 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention is moot and **withdrawn** in view of cancellation of the claim.

Double Patenting

7. Rejection of claim 17 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,128,916 is moot and **withdrawn** in view of cancellation of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 3, 4, 6, 9-16 and 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 02/076498 (J. B. March; 10/3/2002).

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

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The anticipation is clear from a comparison of the claims; for example, claim 1 of the instant Application is within the scope of claims 1 and 3 of the applied reference. Further examples of anticipation follow with the claim of the instant Application followed by the relevant claim of the applied reference in parentheses: 3 (1, 3); 4 (9); 6 (2); 9 (5); 10 (6); 11 (7); 12 (8); 13 (9); 14 (10); 15 (11); 16 (12); 18 (14); 19 (15) and 20 (16). Thus each and every limitation of the rejected claims is clearly anticipated by WO 02/076498.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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10. Claims 5 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/076498. The claims are drawn to an immunogenic composition comprising recombinant bacteriophage capable of expressing hepatitis viral genes in a eukaryotic host and a method of use of the composition. Claim 5 adds the specific limitation of the number of bacteriophage particles in the composition whereas claim 21 is the method claim.

Regarding claim 5: The particular number recited in the claim (10^9 particles) is a result dependent variable that is obvious to optimize and would easily be determined by routine experimentation.

Regarding claim 21: The mere use of the term "vaccine formulation" recited in Claim 1 of the applied reference clearly implies that such formulations raise an immunogenic response.

It would have been obvious to one of ordinary skill in the art to modify the compositions taught by WO 02/076498 in order to produce an immunogen specific to hepatitis viruses. One would have been motivated to do so given the suggestion by WO 02/076498 that viruses are a class of disease-causing agent amenable to vaccination by the common type of immunogen and the common knowledge in the vaccine arts that hepatitis viruses prevented by vaccination.

There would have been a reasonable expectation of success given the knowledge that the method of making bacteriophage-based compositions common to both the applied reference and the instant application are made by common molecular biological methods, as taught by WO 02/076498. Thus, the

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invention of claims 5 and 21 was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on (571)272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/
Primary Examiner, Art Unit 1648

Stuart W Snyder
Examiner
Art Unit 1648

SWS